<div align="center">**Amendments to the Claims**</div>

This listing of claims will replace all prior versions, and listings, of claims in the application:

1. (currently amended) A method for evaluating a clinical trial protocol specification, comprising the steps of:

encoding into a database, workflow tasks called for in a clinical trial protocol specification not yet in execution, including ~~the step of encoding~~ substeps of writing, into protocol specification objects of said database, specifications of protocol events that said protocol specifies to occur during execution of said protocol, and ~~further including the step of encoding, into protocol specification objects of said database,~~ relationships that said protocol specifies among said protocol events;

during said step of encoding workflow tasks ~~called for in a clinical trial protocol specification not yet in execution~~ but not during any of said substeps, identifying an operational uncertainty in which said protocol specification contains at least one of the following deficiencies: said protocol specification fails to specify a particular parameter for use during protocol execution, or said protocol specification specifies such a parameter ~~too vaguely to be encoded into said database~~ with less precision than is required by a slot in said database for encoding the parameter, or said protocol specification ~~specifies such a parameter inconsistently~~ contains at least two such parameter specifications which are in conflict;

encoding into said database in association with at least a particular one of said protocol specification objects in said database, before execution of said clinical trial protocol, an indication that said operational uncertainty exists with respect to said particular object; and

in dependence upon protocol specification objects in said database, before execution of said clinical trial protocol, displaying a graphical-visual representation of said protocol, said graphical-visual representation including a human-perceptible indication that said particular protocol specification object has said operational uncertainty associated therewith.

2. (original) A method according to claim 1, wherein said database is an object-oriented database.

3. (previously presented) A method according to claim 1, wherein said protocol specification objects include protocol event objects describing protocol events, and temporal constraint objects describing temporal constraints among said protocol event objects.

4. (previously presented) A method according to claim 3, wherein said step of displaying comprises the step of displaying each of said protocol specification objects in a color which differs depending on whether an operational uncertainty is associated therewith.

5. (previously presented) A method according to claim 1, wherein said step of displaying comprises the step of displaying each of said protocol specification objects in a color which differs depending on whether an operational uncertainty is associated therewith.

6. (currently amended) A method according to claim 1, wherein said operational uncertainty comprises ~~an inconsistency in said protocol specification~~ said protocol specification containing at least two parameter specifications which are in conflict.

7. (currently amended) A method according to claim 1, wherein said operational uncertainty comprises ~~an insufficiently specified parameter in said protocol specification~~ said protocol specification specifying a parameter with less precision than is required by a slot in said database.

8. (previously presented) A method according to claim 1, wherein said operational uncertainty comprises an omitted parameter in said protocol specification.

9. (original) A method according to claim 1, wherein said operational uncertainty concerns a temporal constraint among at least two of said protocol events.

10. (currently amended) A set of at least one computer readable medium, said set carrying a machine readable database which includes protocol specification objects describing protocol events that a protocol specification specifies to occur during execution of said protocol, and relationships among said protocol events,

said database further including a disambiguation comment object which identifies an operational uncertainty in which said protocol specification contains at least one of the following deficiencies: said protocol specification fails to specify a particular parameter for use during protocol execution, or said protocol specification specifies such a parameter ~~too vaguely to be encoded into said database~~ <u>with less precision than is required by a slot in said database for encoding the parameter</u>, or said protocol specification ~~specifies such a parameter inconsistently~~ <u>contains at least two such parameter specifications which are in conflict</u>, said disambiguation comment object being associated with at least a particular one of said objects in said database.

11. (original) A medium according to claim 10, wherein said database is an object-oriented database.

12. (previously presented) A medium according to claim 10, wherein said protocol specification objects include protocol event objects describing protocol events, and temporal constraint objects describing temporal constraints among said protocol event objects.

13. (original) A medium according to claim 12, wherein said disambiguation comment object is associated with one of said protocol event objects.

14. (original) A medium according to claim 12, wherein said disambiguation comment object is associated with a particular one of said temporal constraint objects.

15. (original) A medium according to claim 14, wherein said operational uncertainty concerns the amount of time allowed to elapse between two protocol events identified by said particular temporal constraint object.

16. (previously presented) A medium according to claim 12, wherein said protocol specification objects further include workflow task objects.

17. (original) A medium according to claim 16, wherein each of said workflow task objects is associated with at least one of said protocol event objects.

18. (original) A medium according to claim 16, wherein said disambiguation comment object is associated with one of said workflow task objects.

19. (currently amended) A medium according to claim 10, wherein said operational uncertainty comprises ~~an inconsistency in said protocol specification~~ said protocol specification containing at least two parameter specifications which are in conflict.

20. (currently amended) A medium according to claim 10, wherein said operational uncertainty comprises ~~an insufficiently specified parameter in said protocol specification~~ said protocol specification specifying a parameter with less precision than is required by a slot in said database.

21. (previously presented) A medium according to claim 10, wherein said operational uncertainty comprises an omitted parameter in said protocol specification.

22. (original) A medium according to claim 10, wherein said operational uncertainty concerns the amount of time allowed to elapse between two of said protocol events.

23. (previously presented) A set of at least one computer readable medium, the set carrying a plurality of machine readable objects instantiated according to a pre-specified class structure, the machine readable objects including protocol event specification objects describing protocol events that a protocol specification specifies to occur during execution of said protocol, and temporal constraint specification objects describing temporal relationships that a protocol specification specifies to occur among protocol events described in said protocol event specification objects, at least a particular one of said temporal constraint specification objects identifying an amount of time that said protocol specifies is to elapse between two or more protocol events when the protocol is executed.

24. (previously presented) A medium according to claim 23, wherein said plurality of machine readable objects are objects of an object-oriented database.

25. (previously presented) A medium according to claim 23, wherein said plurality of machine readable objects further includes workflow task objects.

26. (previously presented) A medium according to claim 23, wherein said amount of time describes the time that a hypothetical patient is expected to take between protocol events described in first and second identified ones of said protocol event objects.

27. (original) A medium according to claim 23, wherein said particular temporal constraint object identifies said amount of time by identifying at least one member of the group consisting of minimum and maximum times.

28. (original) A medium according to claim 27, wherein said particular temporal constraint object identifies said amount of time by identifying both members of the group consisting of minimum and maximum times.

29. (original) A medium according to claim 28, wherein said particular temporal constraint object identifies said amount of time further by identifying a base time between said minimum and maximum times.

30. (previously presented) A medium according to claim 23, wherein said plurality of machine readable objects further includes a disambiguation comment object associated with said particular temporal constraint object, said disambiguation comment object identifying an operational uncertainty in a particular temporal relationship identified in said temporal constraint object.

31. (currently amended) A medium according to ~~claim 23~~ claim 30, wherein said operational uncertainty comprises an inconsistency in one of said temporal relationships as specified in said protocol specification.

32. (currently amended) A medium according to ~~claim 23~~ claim 30, wherein said operational uncertainty comprises vagueness in one of said temporal relationships as specified in said protocol specification.

33. (currently amended) A medium according to ~~claim 23~~ claim 30, wherein said operational uncertainty comprises omission of one of said temporal relationships from said protocol specification.

34. (currently amended) A method for evaluating a clinical trial protocol specification, comprising the steps of:

encoding into a database, workflow tasks called for in a clinical trial protocol specification not yet in execution, said step of encoding including substeps of writing data from said protocol specification into said database, said database being structured according to a predetermined model, said model including slots predefined for describing respective aspects of protocol events that a protocol can specify to occur during execution of the protocol, said model further including slots predefined for describing temporal relationships that a protocol can specify among such protocol events, said slots predefined for describing temporal relationships including slots predefined for describing amounts of time that a protocol specifies are to elapse between two or more protocol events; and

during said step of encoding, but not during any of said substeps of writing, identifying an operational uncertainty in which said protocol specification contains at least one of the following deficiencies: said protocol specification fails to specify an amount of time that is to elapse between two or more protocol events, or said protocol specification specifies such an amount of time ~~too vaguely to be encoded into~~ with less precision than is required by a slot in said database, or said protocol specification specifies such an amount of time ~~inconsistently~~ in conflict with another parameter specified in said protocol specification.

35. (original) A method according to claim 34, further comprising the step of displaying a graphical-visual representation of said protocol, said graphical-visual representation including a human-perceptible indication that said particular amount of time has an operational uncertainty associated therewith.

36. (previously presented) A method according to claim 34, wherein said predetermined model comprises a predetermined object class structure and said slots are organized into protocol specification objects defined by said object class structure.

37. (previously presented) A method according to claim 36, wherein said protocol specification objects include protocol event objects describing protocol events, and temporal constraint objects describing temporal constraints among events described in said protocol event objects, each of said temporal constraint objects including at least one slot for identifying an amount of time allowed between two or more protocol events.

38. (currently amended) A method according to claim 37, further comprising the steps of:
     instantiating a disambiguation protocol specification object defined according to said object class structure describing said operational uncertainty; and
     associating said disambiguation protocol specification object with ~~a temporal constraint object which includes a slot for identifying said particular amount of time~~ one of said temporal constraint objects.

39. (currently amended) A method according to claim 34, wherein said operational uncertainty comprises ~~an inconsistency in said particular amount of time as specified in said protocol specification~~ said protocol specification specifying a particular amount of time in conflict with another parameter specified in said protocol specification.

40. (currently amended) A method according to claim 34, wherein said operational uncertainty comprises ~~vagueness in said particular amount of time as specified in said protocol specification~~ said protocol specification specifying a particular amount of time with less precision than is required by a slot in said database.

41. (currently amended) A method according to claim 34, wherein said operational uncertainty comprises omission of ~~said particular~~ a particular amount of time from said protocol specification.

42. (currently amended) A method for evaluating a clinical trial protocol specification, comprising the steps of:

encoding into a database, workflow tasks called for in a clinical trial protocol specification not yet in execution, including ~~the step of encoding~~ <u>substeps of writing</u>, into protocol specification objects of said database, specifications of protocol events that the protocol specifies to occur during execution of the protocol, and ~~further including the step of encoding,~~ ~~into protocol specification objects of said database,~~ relationships that the protocol specifies among said protocol events;

during said step of encoding workflow tasks ~~called for in a clinical trial protocol~~ ~~specification not yet in execution~~ <u>but not during any of said substeps</u>, identifying an operational uncertainty in which said protocol specification contains at least one of the following deficiencies: said protocol specification fails to specify a parameter for use during protocol execution, or said protocol specification specifies such a parameter ~~too vaguely to be encoded~~ ~~into said database~~ <u>with less precision than is required by a slot in said database for encoding the parameter</u>, or said protocol specification ~~specifies such a parameter inconsistently~~ <u>contains at least two such parameter specifications which are in conflict</u>;

encoding into said database in association with at least a particular one of said protocol specification objects in said database, before execution of said clinical trial protocol, an indication that said operational uncertainty exists with respect to the particular protocol specification object; and

in dependence upon objects in said database, before execution of said clinical trial protocol, outputting a report setting forth the operational uncertainties identified in said protocol and encoded into said database.

43. (currently amended) A method according to claim 42, further comprising the ~~step of~~ ~~associating said particular protocol specification object with at least one of said~~ <u>steps of:</u>

<u>encoding into a protocol disambiguation object said indication that said operational</u> <u>uncertainty exists; and</u>

associating said protocol disambiguation object with said particular protocol specification objects in said database.

44. (currently amended) A method according to claim 43, wherein said protocol specification objects include protocol event objects describing protocol events, and temporal constraint objects describing temporal constraints among protocol events described in said protocol event objects,

and wherein said step of associating comprises the step of associating said ~~particular protocol specification~~ protocol disambiguation object with one of said protocol event objects or one of said temporal constraint objects in said database.

45. (original) A method according to claim 42, wherein said database is an object-oriented database.

46. (original) A method according to claim 42, further comprising the step, prior to said step of outputting, of sorting a list of said operational uncertainties identified in said protocol and encoded into said database.

47. (original) A method according to claim 42, wherein said step of outputting comprises the step of outputting in tabular form the operational uncertainties identified in said protocol and encoded into said database.

48. (currently amended) A method according to claim 42, wherein said operational uncertainty comprises ~~an inconsistency in said protocol specification~~ said protocol specification containing at least two parameter specifications which are in conflict.

49. (currently amended) A method according to claim 42, wherein said operational uncertainty comprises ~~an insufficiently specified parameter in said protocol specification~~ said protocol specification specifying a parameter with less precision than is required by a slot in said database.

50. (previously presented) A method according to claim 42, wherein said operational uncertainty comprises an omitted parameter in said protocol specification.

51. (previously presented) A method according to claim 42, wherein said operational uncertainty concerns a temporal constraint among at least two of said protocol events specification.

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